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10/542,430

07/15/2005

Xiang Dong Liu

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ALEXANDRIA, VA 22320

EXAMINER

CROW, ROBERT THOMAS

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/542,430

Applicant(s)

LIU ET AL.

Examiner

Robert T. Crow

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II in the reply filed on 23 April 2007 is acknowledged. The traversal is on the ground(s) that all of the claims include the same special technical feature. This is not found persuasive because Sloma et al (U.S. Patent No. 4,663,280, issued 5 May 1987) disclose contacting plasmid DNA, which is double stranded, with a solution of ethidium bromide, which is an intercalating harmful substance. The DNA having the intercalated ethidium is then separated by centrifugation and dialysis against TE buffer (column 5, lines 35-50).

Therefore, as stated in the Requirement for Restriction dated 23 March 2007, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Applicant further argues that the subject matter of claims 1-6 is sufficiently related that a search of any one group would encompass a search of the remaining groups; i.e., the search would not be burdensome.

However, the claims of the instant 371 national stage application were found to lack unity of invention (where unity of invention requires a special technical feature) due to the lack of a special technical feature between the different groups. Thus the burden of the search of these different inventions is moot.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2 and 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 23 April 2007.

Claim 3 is under prosecution.

*Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in the recitation "characterized by comprising" in line 2 of the claim. It is unclear if "characterized by" refers to structural limitations of the adsorbent or if "characterized by" refers to an active step used to characterize the claimed adsorbent. Because the claim is drawn to an adsorbent, it is suggested the claim be amended to delete the phrase "characterized by" so that the claim is clearly limited to the structural limitations of the claimed adsorbent.

Claim 3 is also indefinite in the recitation "a container or a bag made of a membrane...for the double-stranded DNA" at the end of the claim. The placement of the word "or" renders the claim unclear as to whether the container is required only to be a container, a container permeable to a harmful substance, or a container made of a membrane that is permeable to a harmful substance. It is suggested that the claim be amended to clarify whether the precise structural limitations required for the instantly claimed container.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Hershberger et al (U.S. Patent No. 4,436,815, issued 13 March 1984).

Regarding claim 3, Hershberger et al teach an adsorbent. In a single exemplary embodiment, Hershberger et al teach an adsorbent comprising double-stranded DNA in the form of restriction fragments of plasmid (i.e., double-stranded) DNA having sticky ends (column 8, lines 9-45). The double-stranded DNA fragments are enclosed in a bag made of a membrane that is permeable to a harmful substance but is not permeable to the double-stranded DNA; namely, the double-stranded DNA is in a dialysis bag (column 8, lines 9-45). The dialysis bag is a membrane that is permeable to the harmful substance ethidium bromide but not to the double-stranded DNA because the ethidium bromide is dialyzed away from the double-stranded DNA, which stays in the bag (column 8, lines 9-45).

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 3 (e.g., removing a harmful substance) fail to define additional structural elements to the adsorbent of claim 3. Because Hershberger et al teach the structural elements of claim 3, the claim is anticipated by Hershberger et al. See MPEP § 2114.

6. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Liu et al (Int. J. Biol. Macromol., vol.32, pages 121-127 (2003)).

Regarding claim 3, Liu et al teach an adsorbent for removing harmful substances. In a single exemplary embodiment, Liu et al teach an adsorbent comprising double stranded DNA in the form of a dialysis bag having a solution of double stranded DNA therein (page 122, paragraphs 2.1 and 2.4). The dialysis bag is a membrane that is permeable to dioxins, which are harmful substances, but not to the

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double-stranded DNA because the dioxins are dialyzed away from the double-stranded DNA, which stays in the bag ("Conclusions," page 127 ).

7. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al (Environ. Sc. Tech. vol.36, pages 949-954 (2002)).

Regarding claim 3, Yamada et al teach an adsorbent for removing harmful substances. In a single exemplary embodiment, Yamada et al teach an adsorbent comprising double stranded DNA in the form of a porous glass bead having double-stranded DNA immobilized therein (pages 949-950, paragraphs 2.1 and 2.3). The porous glass bead is a container that is permeable to dioxins, which are harmful substances, but not to the double-stranded DNA because the double-stranded DNA is crosslinked to the porous glass (page 950, paragraph 2.3).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). Because the glass beads have pore sizes of approximately 100 microns (page 949, paragraph 2.1), at least some of the DNA is immobilized within the pores of the bead, and is thus "contained" within the bead.

8. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Mirkin et al (U.S. Patent No. 6,361,944, issued 26 March 2002).

Regarding claim 3, Mirkin et al teach an adsorbent for removing harmful substances. In a single exemplary embodiment, Mirkin et al teach as adsorbent comprising double stranded DNA in the form of a cuvette containing double-stranded DNA (Figures 4 and 6 and column 13, lines 48-62). The cuvette is a container.

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As noted above, apparatus claims cover what a device *is*, not what a device *does*." Therefore, the various uses recited in claim 3 (e.g., removing a harmful substance) fail to define additional structural elements to the adsorbent of claim 3. Because Mirkin et al teach the structural elements of claim 3, the claim is anticipated by Mirkin et al.

### *Double Patenting*

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 3 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/479,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an adsorbent (i.e., a trapping filter) for harmful substances comprising a double stranded DNA in a container; i.e., the fibrous filter material of the '462 claims has DNA supported among the fibers, and thus contains the double stranded DNA therein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


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*Conclusion*

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



RAM R. SHUKLA, PH.D.  
SUPERVISORY PATENT EXAMINER

Robert T. Crow  
Examiner  
Art Unit 1634

